UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

January 29, 2009

DP BARCODE:	**# 357917 (amended review)**
MRID:	**# 475753-01, # 475753-02**
SUBJECT:	**Reflexx**
REG. NO. OR FILE SYMBOL:	**63838-RE**
DOCUMENT TYPE:	**Product Chemistry Review**
Manufacturing-use [] **OR**	**End-use Product [X]**
INGREDIENTS (PC Codes)	**Hydrogen peroxide (000595), Peroxyacetic acid (063201)**
CAS Number:	**7722-84-1, 79-21-0**
TEST LAB:	**Enviro Tech Chemical Services, Inc.**
SUBMITTER:	**Enviro Tech Chemical Services, Inc.**
GUIDELINE:	**OPPTS Guideline Series 830 for Group A and Group B**
COMMODITIES:	**New End-Use Product**
REVIEWER:	**Alex Traska**
ORGANIZATION:	**AD**
APPROVER:	**Karen P. Hicks** **APPROVED DATE:**

COMMENT:

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MEMORANDUM

Subject: Review for EPA Reg. No. 63838-RE

From: Alexander W. Traska, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell PM #33
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Enviro Tech Chemical Services, Inc.
Action Code: (A540) New Product; Non-fast track
Due out date: 10 Mar 2009

Formulations from Label

Active Ingredient(s)	% by wt.
Peroxyacetic acid	6.1
Hydrogen peroxide	23.0
Other Ingredients	70.9
Total	100.0

Product ingredient source information may be entitled to confidential treatment

I BACKGROUND

This new product registration, for the subject acid sanitizer for use on food, dairy and beverage processing equipment was submitted the registrant, Enviro Tech Chemical Services, Inc.

The registrant, in this new product application, has requested approval to register the new end-use product, **Reflexx**. The product is for use as a sanitizing rinse on hard, non-porous, food contact surfaces, including food, dairy, and beverage processing equipment, tanks, pipelines and closed systems. The data package included a Confidential Statement of Formula (CSF) for the pre-reaction basic formulation (dated October 23, 2008) and a CSF for the post-reaction basic formulation (dated October 23, 2008). The product is produced by an integrated formulation system (i.e., the product contains, peroxyacetic acid, an active ingredient that is not an EPA-registered product). The registered product, [redacted] is the source of the active ingredient, hydrogen peroxide.

The following documents were submitted and examined in the chemistry review of this submission: new Basic CSF (pre and post-reaction) dated January 28, 2009, Basic CSF (pre- and post-reaction) dated October 23, 2008 (obsolete, replaced by January 28, 2009 Basic CSF) , proposed new product label dated 9/08, Data Matrix (Agency copy) dated October 2, 2008, OPPTS 830.1750 Certification Statement dated January 28, 2009, Group A product chemistry data submitted under MRID # 475753-01 dated October 15, 2008 and Group B product chemistry data was submitted under MRID # 475753-02 dated October 15, 2008.

A preliminary chemistry review of this new product registration was made by CSC Systems & Solutions LLC and all relevant comments from the December 22, 2008 CSC review were incorporated into this Product Chemistry Review.

II FINDINGS

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients given in the new post-reaction Basic CSF, dated January 28, 2009, agreed with the percentages declared on the product label.

2. [redacted] is the registered source of the active ingredient, hydrogen peroxide. The peroxyacetic acid is formed in the integrated manufacturing system and is not EPA-registered.
The other ingredients utilized in the pre- and post-reaction formulations are found in the Agency's inert database and are accepted for use in pesticide formulations.

3. The upper and lower certified limits for both the active and inert ingredients are accepted.

4. This sanitizer is approved for food-contact surfaces as per 21CFR 178.1010 (b) (30) and (c) (25).

5. The study report under MRID # 475753-01 contained data responding to the requirements of OPPTS Test Guideline Series 830, Group A. The Group A product chemistry data requirements applicable to end-use products have been met.

The OPPTS 830.1700(Preliminary Analysis of Active Ingredients) study was done under the requirements of 40 CFR Part 160 Good Laboratory Practice (GLP). Analytic data generated in the five batch preliminary analysis for peroxyacetic acid are accepted.

6. The study reports under MRID # 475753-02 contained data responding to the requirements of OPPTS Test Guideline Series 830, Group B. The Group B product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics). To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. The concentration of the active ingredients in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year.

The Storage Stability and Corrosion Characteristics studies are in progress and are to be submitted to the Agency on completion.
A statement of Good Laboratory Practice (GLP) compliance was provided for the study assigned MRID 475753-02. The physical and chemical characterizations presented in the study were conducted in accordance with GLP standards (40 CFR Part 160).

7. The following revisions to the product label should be made:

- Move the following text from the "Pesticide Disposal" section of the product label to the "Container Disposal" section of the product label: "Clean container promptly after emptying. Offer for recycling if available."

- Add the following text to the "Container Disposal" section of the product label: "Or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."

- Change the EPA registration number from "63838-12" to "63838-____."

- Under the "Directions for Use" section of the product label, change "previously cleaned food-contact surfaces" to read "previously cleaned, hard, non-porous, food contact surfaces."

- Under the "Precautionary Statements" section of the product label, change "an enclosed area" to read "an enclosed area where this product has been applied."

- Under the "Precautionary Statements" section of the product label, change "breath vapors" to read "breathe vapors."

- Under the "Precautionary Statements" section of the product label, change "before eating, drinking, or using tobacco" to read "before eating, drinking, chewing gum, using tobacco, or using the toilet."

- Under the "Environmental Hazards" section of the product label, change "National Pollution Discharge Elimination System (NPDES) permit" to read "National Pollutant Discharge Elimination System (NPDES) permit."

- Under the "Procedure for Leak or Spill" section of the product label, change "is sprinkle area" to read "is to sprinkle the area."

- Under the "If in Eyes" section of the product label, change "contact lenses of present" to read "contact lenses if present."

III CONCLUSIONS

This new product application, which requested approval to register the proposed new end-use product **Reflexx,** is accepted.

Registrant is requested to address the comments and recommendations listed above in items #6 and #7 of the Findings.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [ ]

Note: All active and inert ingredients are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated on January 7, 2008 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [ ] No [X]

Note: The pH reported on the post-reaction CSF must be corrected to read "1.78."

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient(s)

	NC (%)	LCL (%)	UCL (%)
Peroxyacetic acid	6.1	5.79	6.41
Hydrogen peroxide	23.00	22.31	23.69

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?

Yes [ ] No [ ] Not applicable [X]

- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X]
No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [ ] No [ ]

Note: Revisions to the "Pesticide Disposal" and "Container Disposal" sections of the product label must be made. See the "Recommendations" section of this report for details.

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: Storage stability studies are ongoing and have not been completed.

Note: The product label includes the following statement: "This product degrades with age depending on the storage conditions and temperature. Use a peroxyacetic acid test kit and increase dosage as necessary to obtain the required level of active ingredients."

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	475753-01 and CSF
830.1600 Description of Materials	A	475753-01
830.1620 Production Process[2]	A	475753-01
830.1650 Formulation Process[3]	NA	
830.1670 Formation of Impurities[4]	A	475753-01
830.1700 Preliminary Analysis[5]	A – Results from the analysis of five batches of the product were provided. Note: In some cases, active ingredient concentrations of the analyzed batches exceeded the proposed upper certified limits. Page 27 of the study assigned MRID 475753-01 suggests that this may happen, and that batches slightly above the upper certified limits will be released for sale "because the degradation of the active ingredients means that by the time the Reflexx product gets to the end-user, the concentration of the active ingredients will" be well within the proposed certified limits.	475753-01
830.1750 Certified Limits[6]	A – Standard certified limits were proposed for the post-reaction product.	475753-01 and CSF
830.1800 Analytical Method[7]	A – A copy of a titration method was provided for determining peroxyacetic acid and hydrogen peroxide concentrations in the product.	475753-01
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.

[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The product is colorless, based on visual inspection.	475753-02
830.6303 Physical State	A	The product is a liquid at 20°C, based on visual inspection.	475753-02
830.6304 Odor	A	The product has a pungent, vinegar-like odor at room temperature.	475753-02
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	A qualitative discussion, based on knowledge of the product's chemistry, was provided. The product contains peracetic acid and hydrogen peroxide. These compounds are common oxidizing agents that impart the solution with their oxidizing properties. Thus, contact of the product with easily oxidizable organic compounds such as alcohols, aldehydes, and thiols should be avoided. Strong reducing agents such as nitrites, sulfides, sulfites, metabisulfites, and	475753-02

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		thiosulfates are incompatible, and their contact with the product should be prevented. Both peracetic acid and hydrogen peroxide react slowly with ammonia, organic ammonium compounds, and inorganic ammonium compounds. Thus, the product should never be mixed with ammonia-containing products. Similarly, the product should not be used to contact monoammonium phosphate fire extinguishing agents. Peracetic acid and hydrogen peroxide are very aggressive to soft metals such as iron, copper, zinc, and brass. Stainless steel is the only metal that should be allowed to contact the product. Stainless steel and plastic materials (e.g., high density polyethylene (HDPE), polypropylene, polytetrafluoro- ethylene, polyvinylidene fluoride, polyvinylchloride) are suitable for storage, piping, and pumping solutions of the product. The product should be packaged in containers constructed of HDPE only. Tanker trucks used to transport solutions of the product should be constructed of stainless steel or fiber-reinforced plastic. Note: The product label includes a "Physical or Chemical Hazards" statement.	

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		The product label also includes additional precautionary statements under the "Storage and Disposal" and "Directions for Use" sections.	
830.6315 Flammability/ Flame Extension	A	The product is not a combustible liquid.	475753-02
830.6316 Explodability	A	The product has no constituents with chemical bonds or functional groups associated with explodable chemicals.	475753-02
830.6317 Storage Stability	G	A storage stability study is currently underway. Results will be provided to EPA once the study is complete. Note: The product label includes the following statement: "This product degrades with age depending on the storage conditions and temperature. Use a peroxyacetic acid test kit and increase dosage as necessary to obtain the required level of active ingredients."	475753-02
830.6319 Miscibility[1]	A	The product is not an emulsifiable liquid intended to be diluted with petroleum solvents.	475753-02
830.6320 Corrosion Characteristics	G	A corrosion characteristics study is currently underway. Results will be provided to EPA once the study is complete.	475753-02
830.6321 Dielectric Breakdown Voltage	A	The product is not intended for use around electrical equipment.	475753-02
830.7000 pH[2]	A	The mean pH of the product was reported to be 1.78 at 22.3°C. A 1% w/w solution of the product in deionized	475753-02

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		water was tested. Two determinations were made. Testing was conducted in compliance with GLP.	
830.7050 UV/Visible Absorption	NA	*[Not required for end-use products.]*	
830.7100 Viscosity	A	The mean kinematic viscosity of the product was reported to be 1.3 mm^2/s at 20.0°C and 1.0 mm^2/s at 40.0°C. Methods ASTM D 445, ASTM D 446, ISO 3104, and ISO 3105 were referenced. Testing was conducted in compliance with GLP.	475753-02
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The mean density of the product was reported to be 1.1945 g/mL (9.96 lb/gal) at 23.6°C. Three determinations were made. Testing was conducted in compliance with GLP.	475753-02
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C[1]If product is an emulsifiable liquid

[2]If product is dispersible with water